



**Sub-Regional FAO/UNESCO Workshop  
Agricultural Biotechnology and Biosafety For Food Security and Rural  
Development in the Caucasus Region and Moldova  
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**‘New Biosafety and Bioterrorism Regulations Implemented by the U.S. Food &  
Drug Administration’**

by

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Good afternoon. My name is Jeffrey Engels. I am the Acting Director of the United States Department of Agriculture’s Marketing Assistance Project or MAP in Armenia. MAP is an agribusiness development project that was established in 1996 to assist farmers and agribusinesses in producing, marketing and exporting food and related products to increase incomes, create jobs, and raise the standard of living for rural Armenians. We provide technical, financial, and marketing assistance to over 60 small and medium-sized agribusinesses and we are active in every marz. Our clients include wineries, fruit and vegetable processors, cheese makers, water bottlers, meat processors, food packaging enterprises, and other agribusinesses. We work on every link of the marketing chain—from farm gate to fork, as it were, and increasing food quality and quantity are at the core of all our activities. We firmly hold that high food safety concerns serve to protect and promote the health of the consumer. The production, distribution, and consumption of food are central to any society, and have economic, social, and health consequences. In the aftermath of September 11<sup>th</sup> and the potential for food bioterrorism, public safety is an even greater concern.

Food that is safe to eat and is available in sufficient supply has always been and continues to be a goal of Mankind. Historically, infections and poisons induced in food have been time-honored methods of assassination, siege, and terrorism. In the Middle Ages, royal court tasters were as much a part of an aristocratic entourage as court jesters. Over the past century food safety and sufficiency has transitioned from a household necessity to a public expectation. The modern world’s capacity to grow, harvest, process, and market foodstuffs is a great achievement for human health, but it has not developed without vulnerability to natural and artificial adulteration and contamination.

Over the past 20 years in the United States there have been several cases of deliberate food contamination: in 1984 members of a religious cult contaminated salad bars with *Salmonella typhimurium* in order to disrupt a local election, resulting in 751 cases of salmonellosis and the hospitalization of 45 victims. As recently as May 2003, an American supermarket employee pleaded guilty to intentionally poisoning 200 pounds of

ground beef with an insecticide, sickening 111 people. Examples of food sabotage can be drawn from other countries' experiences as well. In Canada in 1970, a postgraduate student tainted his roommates' food with a parasite, causing four people to be seriously ill and two of these suffered respiratory failure. A dozen children in Holland and West Germany were hospitalized in 1978 after citrus from Israel was deliberately contaminated with mercury. In September 2002, 40 people died and 200 were hospitalized near Nanjing, China, after the owner of a fast-food outlet poisoned a competitor's breakfast food with rat poison.

Food can be employed as an effective weapon and the choice of targets depend on the motivations and objectives of the perpetrators. If the motive is terrorism, enough casualties can produce mass fear, destroy confidence in a food system, and at the very least devastate a market for particular food products or producers. Destroying farmlands and crops are among the oldest uses of food as a weapon: the destruction of farms, crops, and food supplies has long been a tactic of warfare between nations and armies. As food processing and distribution has become more complex and globalized, people are more than ever dependant upon others for a steady supply of food to avoid malnutrition and starvation, and avert food-borne poisoning or infection.

Food is a natural vehicle for pathogenic microbes and toxins. Cyanide, arsenic, nitrates, thallium, anatoxin A, botulinum toxins, and ricin are all deadly. Contaminating or adulterating food or water supplies aimed at target populations are methods terrorists can employ for revenge, to promote ideological principles, or for other reasons. Food bioterrorists can come in numerous forms—from the disgruntled, angry individual to an ideologically-drive group. An outbreak of a disease can immediately shut down civil services, airports, and military bases. Schools with centralized kitchens are prime targets for food bioterrorists: in fact, schools are such a public concern and community focus that a hostile act against them can destroy a community.

In today's global marketplace, the contamination of food in one country can have a significant effect on public health in other parts of the world. In 1989, approximately 25,000 people in 30 U.S. States were sickened by cantaloupes imported from Mexico. In 1996 and 1997, 2500 people in 21 States in the U.S. and two Canadian provinces developed infections after eating tainted Guatemalan raspberries.

The events of September 11, 2001 gave rise to concerns about unconventional terrorists attacks, including the threat of attacks on the U.S. food supply. In the aftermath of that incident, on June 12, 2003 President George W. Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes a large number of provisions to help ensure the safety of the U.S. from bioterrorism, including new authority for the Secretary of Health and Human Services (HHS) to take action to protect the nation's food supply against the threat of intestinal contamination. The Food and Drug Administration (FDA), as the food regulatory arm of the HHS, is responsible for developing and implementing these food safety measures, including four major regulations.

The new FDA regulations cover food and food products. They cover foreign and domestic manufacturers and suppliers of food and food products. They cover warehouses that may store food and food products, as well as exporters, importers, and carriers of food and food products. This includes about 16% of all imports into the United States. And this affects Armenian food and beverage products sold to America.

Since its inception, the USDA Marketing Assistance Project has focused on critical links in the marketing chain. Mindful of the continuing goal to assist Armenian agribusinesses establish themselves, grow, and prosper, the USDA's activities have always included export market promotion and expansion. Emphasis has been placed on producing agricultural products of high enough quality and in sufficient quantity to help either fill existing demand in international markets or improve existing products and create new brands for markets. Too often in Armenia trading on international markets has been viewed as an aside, or bonus, to the main transactions that occur domestically. MAP has adopted an export-oriented approach to help Armenian agribusinesses gain access to markets where growth rates dramatically exceed those at home. This year, for example, over 80 tons of cheese, 100 tons of processed fruits and vegetables, and 80 tons of tomato paste were exported to the United States as the direct result of help by the USDA to Armenian small- and medium-sized agro-processors.

Now the USDA is embarking on an aggressive campaign to promulgate the new FDA food safety measures, specifically major regulations addressing---Prior Notice (of a shipment); Registration (of the domestic importer and foreign exporter); Establishment and Maintenance of Records (required by both the buyer and the seller), and Administrative Detention (which will occur if all documents aren't in order).

Beginning on December 12, 2003, the FDA must receive advance notice of each shipment of food into the U.S. The notice must include a description of all articles, each article's manufacturer and shipper, grower (if known), originating country, country from which the article is shipped, and anticipated port of entry. No later than December 12, 2003, domestic or foreign facilities that manufacture, process, pack, distribute, receive, or hold food for human or animal consumption must register with the FDA. In addition, persons who manufacture, process, pack, transport, receive, hold, or import food will be required to create and maintain records that the FDA determines are necessary to identify the immediate previous sources and immediate subsequent recipients of food. And finally, if the aforementioned are not complied with upon entry at the American port of debarkation, the FDA has the authority to detain the shipment, or if it has credible evidence or information indicating there is a threat of serious adverse health consequence to humans or animals.

To promulgate these FDA regulations and help Armenian agro-processors, food exporters, brokers, freight-forwarding companies, and others to understand these and properly register their food and beverage shipments, the USDA is working closely with Agrogitaspiur—the Armenian Extension Service, integrated with and operating out of the Armenian Agricultural Academy, to hold a series of marz-centered workshops. All the necessary documents and forms have been translated into Armenian so each workshop participant can be walked through the process. Invitations will be dispatched to the

Armenian government, food processors, marz agricultural representatives, ASC staff, Customs personnel, and others. Five sessions will cover all marzes:

17 November 2003---Kotayk & Gegharkunik

19 November 2003—Ararat & Vayots Dzor

21 November 2003—Tavush and Shirak and Lori

24 November 2003—Aragatsotn & Armavir

26 November 2003—Syunik

In addition, representatives from the USDA Foreign Agricultural Service from the U.S. Embassy in Moscow will be on hand to answer questions. The USDA is working hard to assure there is no interruption of Armenian food exports to the United States by these new American biosafety measures.

Deliberate or accidental contamination of food can have enormous implications on a country. The U.S. is not exempt. These FDA regulations go toward strengthening the U.S.' ability to efficiently and effectively help protect the nation's food supply. The USDA Marketing Assistance Project is here in Armenia to help agricultural producers and shippers seamlessly comply with these new rules and continue to grow their exports to meet the demand in America for Armenian food and beverage products.

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